

REMARKS

This is a response to office action dated July 5, 2005. Claims 1-7, 9-26, and 33-72 are currently pending. Claims 71 and 72 are newly added. Claims 71 and 72 find support, for example, in Figures 3A, 3B, and 3C. The figures clearly show the opening of dispenser 46 pointed at and facing the stent.

The numbered paragraphs below correspond to the Examiner's numbered paragraphs:

1. The Examiner has indicated that “[n]ewly submitted claims 54-70 are directed to an invention that is independent or distinct from the invention originally claimed” because (1) “original claims are directed to the use of temperature to either inhibit or induce evaporation of solvent from a coating based on the volatility of the solvent”; and (2) “new claims require a the use of a holding fixture.”

Claims 54 and 61 have been amended to recite “**to either inhibit or induce evaporation of the solvent**” based on the volatile properties of the solvent or based on the volatility of the solvent. Accordingly, Applicants respectfully submit that the first of the two grounds of restricting claims 54-70 is not longer applicable.

With respect to the Examiner's contention that the new claims require the use of a holding fixture while the elected claim set does not require one, Applicants respectfully submit that the Examiner is in error. Elected and examined claim 51 recites, “wherein the **stent is supported by a support assembly**.” Elected and examined claim 52 recites, “wherein the **stent is supported by a support assembly**.” Applicants have amended claim 54 and 61 to a “support assembly,” for consistency with the claim language already considered and approved by the Examiner.

2. The Examiner has indicated that:

Newly submitted claims 37-40, 42, 43, and 47 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: examined claims (such as claim 3) were directed to the simultaneous application of composition and gas. The newly-added claims require termination of spraying composition prior to directing the gas or require the spraying and directing to occur in sequence. Simultaneous application and sequential application are distinct species.... Claim 7 has been modified to embody the second species.

Claims 7, 37-40, 42, 43 and 47 have been withdrawn as being directed to an independent and distinct invention. In making this type of a restriction requirement, the Examiner is bound to group together species that are considered clearly unpatentable over each other. Accordingly, it should be noted on the record that in making this restriction requirement, the Examiner has conceded that the species included in claims 7, 37-40, 42, 43, and 47 are clearly patentable, i.e., novel and not obvious, over the claims of the present application. Applicants are fully reserving all rights to pursue these claims in a divisional application, should the rejoinder of these claims in the current application not be possible.

3./4. Claims 13, 16, 23-26, 33, 44-46, and 48-53 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. **The Examiner has indicated that although the specification supports “directing a gas onto” the device, the Examiner is unable to find any reference about “directly” blowing gas onto the device.**

Applicants respond as follows:

(A) The word “direct” is found all over the specification. “Directing” is a gerund of “direct” (gerunds being special forms of verbs ending in “-ing”). “Directly” is an adverb of “direct.” The word “direct” is the root word for “directly” and “directing.” All three words have the same dictionary definition. Accordingly, the specification has support for the word

“directly” unless the USPTO has changed its rules that an Applicant has the duty to have each word specifically listed in its noun, verb, gerund, infinitive, adverb and adjective form.

(B) The specification specifically recites “a **blower 46 for directing a gas onto the stent**” (see page 8, line 12; *see also*, “**stream of gas directed by blower**” on page 9, line 4). Applicants would respectfully like to break this sentence down for the Examiner’s edification:

(i) One of ordinary skill in the art (or even for that matter, a lay person) knows that a “blower” is a device that “blows” for example a “fan” (see Webster’s II New Riverside University Dictionary). The blower 46, therefore “blows” gas as described in the specification. In Example 7, Applicants have even provided one example of the blower 46 that can be used by Conair Corporation, East Windsor, NJ. Further, Applicants have even stated that the blower is for “blowing” on page 25, line 1.

(ii) Applicants have recited that the blower is for “directing” of the gas. As indicated in paragraph (A) “directing” is a gerund of “direct.” Applicants realize that they did not use this word as an adverb in the specification, but submit that the definition is still the same. Applicants submit that it should be sufficient for written description purposes that the verb (“direct”) or gerund (“directing”) were used throughout out the specification in support of a claimed adverb.

(iii) A blower, which blows gas, is directing the gas “onto” the stent. “Onto” is defined as “to a position on or upon.”

Now, to put (i), (ii) and (iii) together, a sentence which clearly states that “a blower (which is a device for blowing a gas) blows a gas in the direction of and upon the stent” is the same exact thing as “directly blowing the gas onto the device.” There is absolutely no difference between these two sentences. Accordingly the specification provides ample written description support of what has been claimed.

(C) Page 12 of the specification provides that the flow speed of the gas out of the blower and onto the stent can be from 300 feet/minute to about 10,000 feet/minute. Other ranges have

also been provided. Applicants have even provided an example of the flow speed of the gas out from the blower.

(D) Applicants direct the Examiner's attention to Figures 3A, 3B, and 3C, where the end or mouth of the **blower nozzle is directly pointed at and facing the stent**. Applicants do not understand how much more clearly this can be illustrated. In the specification, Applicants have even provided specific examples of the distance between the blower nozzle and the stent (for example, 4 cm).

With all due respect, Applicants are very dumbfounded of what more of a written description requirement is needed to support the claims. The Applicants have fully described what has been claimed, have provided specific figures illustrating examples of what has been claimed, and have provided specific working examples describing and enabling what has been claimed. Removal of the rejection is respectfully requested.

5./6. Claims 13, 16, 23-26, 33, 44-46, 48-53 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. The Examiner has two points of contention: (I) that the word "directly" is indefinite; and (II) the phrase "the blowing does not affect the direction of the spray onto the device" is unclear.

I. With respect to the first point, Applicants submit the following:

A. The term "directly" has not been deemed as being indefinite by the United States Patent and Trademark Office as well as the courts. In fact it has been claimed many times without it being deemed indefinite. For example, U.S. Patent No. 6,300,641 **claims** "*blowing* a 1-8 ml/min of reactive *gas directly* onto the ITO or glass surface under a vacuum condition." U.S. Patent No. 6,342,104 **claims** "*directly blowing* inert *gas* against said object on

transportation.” U.S. Patent No. 6,474,986 claims “wherein the nozzle is provided to jet the cooling *gas directly* to the wiring connector.”

The Examiner’s holding that the term is indefinite is arbitrary and capricious. Applicants respectfully submit that the Examiner, as an agent of the United States Patent and Trademark Office, is supposed to be representing the views, holdings and finding of the United States Patent and Trademark Office and not her own individual views of what is or is not indefinite. The public has every right to rely on past decisions of the USPTO in drafting claims that have already been accepted and approved by the USPTO. The Examiner should not be able to subjectively decide what she considers to be indefinite. The Examiner’s holding of “directly” being indefinite not only lacks case law support, but also flies in the face of many decisions holding that this term is in fact definite.

B. The case law is very clear in that although a claim language may include terms of degree, which may not be precise, this does not automatically render the claim indefinite under 35 U.S.C. § 112, second paragraph. Seattle Box Co. v. Industrial Crating & Packaging Inc., 731 F. 2d 818, 221 U.S.P.Q 568 (Fed. Cir. 1984). Acceptability of the claim language depend on whether one of ordinary skill in the art would understand what is claimed in light of the specification. MPEP 2173.05b. Considering that figures have been provided that illustrate the mouth of the nozzle being pointed right at and facing the stent (see Figures 2, 3A, #B and 3C), considering that the specification provides exact numbers as to the flow rate of the air or gas out from the nozzle (e.g., 300 ft/min to 10,000 feet/min and 2500 ft/min to 6000 ft/min), considering that the specification provides specific, working examples of how far the nozzle of the blower has to be positioned (e.g., 4 cm or 8cm), and considering that such terminology has been adequately discussed in prior patents, Applicants submit that one of ordinary skill would be reasonably appraised of the scope of the invention.

It should be noted and emphasized that the standard is “reasonably appraised” and not “appraised beyond the shadow of a doubt” about the scope of the invention. Applicants respectfully submit that the Examiner has completely brushed over the standard of review of “reasonableness” and she is requiring an absolute standard of appraisal of the scope of the invention.

C. The Examiner states that “directly” is a matter of “degree” and therefore indefinite. Applicants respectfully disagree. There is “directly” and there is “indirectly.” There are no other English words that define a term that lies between “directly” and “indirectly.” If there is one, Applicant would be curious to know what it is. There is no matter of degree embedded in this term. The term is defined as to “to move in a direct or straight course” (Webster’s II New Riverside University Dictionary). Even if, for the sake of argument, the term was a matter of degree, terms, such as, “about,” “essentially,” and “substantially,” have been found to be definite. Applicants fail to see how “about” or “substantially” are more “definite” than “directly.” Considering that the Figures clearly illustrate the blower directed at and facing the stent, Applicants submit that blower is directly blowing gas onto the stent and not away from the stent.

D. On page 7 of the office action, with respect to the 112 rejection, the Examiner has stated that “[t]he specification does not provide requirements for the path the gas must take, the speed the gas must possess, or the distance the dispenser must be from the substrate in order to meet the limitation of “directly.” With all due respect, Applicants find this statement very disconcerting based on the fact that the specification does teach an example for each disclosure that the Examiner is claiming that is missing from the specification. The Figures illustrate the blower directly pointed at or facing the stent; the specification provides exemplary numbers as to the flow rate of the air or gas out from the nozzle (e.g., 300 ft/min to 10,000 feet/min or 2500 ft/min to 6000 ft/min); and the specification provides specific examples of the distance of the gas dispenser from the stent e.g., 4 cm or 8 cm.

In light of the above comments, Applicants respectfully request removal of the rejection.

II. With respect to the second point (that the phrase, “the blowing does not affect the direction of the spray onto the device is unclear,” Applicants submit the following:

The Examiner appears to not be sure of how a gas can be directed at a spray and yet not affect the direction of the spray. Applicants respectfully do not understand the Examiner point of contention. By way of analogy, if a 1 mile an hour wind is blown onto a side of a moving car, the direction of the car would not change. On the other hand, if a 100,000 mile per hour wind is blown onto the side of the moving car, the direction of the car will change. The same fluid dynamic engineering principle applies here. Should the Examiner need some kind of fluid flow analysis model from the Applicants showing how a flow of gas need not affect the direction of a spray, Applicants would be more than happy to provide that for the Examiner.

8. Claims 1-6, 11, 13, 17-19, 21-24, 33-36, 44, 46, and 48-53 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Castro et al. (U.S. 6,395,326). Applicants respectfully disagree and submit the following:

A. Castro fails to teach “**directing a gas, from a gas dispenser positioned at a distance from the coating dispenser, onto the implantable medical device.**”

(1) On page 6 of the office action, the Examiner states that “Applicants speculates that a charged, glowing pin may be positioned in the orifice of the nozzle and used for the application of heat.” It is true that this “speculation” was made by the Applicants. **However, the only reason that this speculation was made is to rebut a speculation made by the Examiner that the reference teaches blowing of gas.** The Examiner’s argument that Castro teaches blowing of a gas is just as much of a speculation as that of the Applicants’ speculation – there is no

difference. The fact of the matter is that Castro has absolutely and unequivocally no teaching about directing a gas and the Examiner is speculating about missing claimed elements.

Applicants, with all due respect, submit that they find it ironic that the Examiner is accusing the Applicants of responding by speculation while the foundation of the rejections made by the Examiner is embedded in speculations and conjectures.

(2) On page 6 of the office action, the Examiner states that “conduits are used for conveying fluids, nozzles are used as projecting vents, and orifices are openings.” Based on this teaching, the Examiner is “speculating” that Castro must teach blowing of gas. Applicants would like to provide a speculation in response to the Examiner’s speculation – namely, **conduits are also used for housing electrical wires, nozzles are also used to direct heat to a certain direction (such as directing the heat of a glowing pin) and to prevent the glowing pin from making inadvertent contact with the coating to damage the coating, and orifices are used to allow heat from a glowing pin to discharge out of the nozzle.**

Finally, Applicants would like to point out that their speculation is much more reasonable than the speculation made by the Examiner based on the teaching of Castro as a whole. First, Castro teaches that the heating nozzle 56 is made from metal, glass and high-temperature plastics. These materials are more likely to be used with heating pins as opposed to gas blowers. Second, Castro teaches capability of “discretely” heating very small areas of struts, such as cavities. A flow of gas is much harder to regulate or localize than heat emitted from a heating pin. Third, Castro teaches that the heating conduit and nozzle are connected to control and motion systems. It would be difficult to connect a heating pin to a motion control system as well as a controller, for controlling the operations of the heating pin, without the use of wires and the like that need to be run through a conduit.

The fact of the matter is that the Examiner is speculating about the teaching of Castro and the Applicants are rebutting the speculation with a counter speculation. The bottom line is that Castro has no teaching about directing of the gas.

(3) On page 6, the Examiner has noted that “[s]ince Castro does not teach conveying and projecting of a warm liquid (as such would wet, not dry the coating), it is immediately clear to an ordinary artisan that Castro is conveying and projecting gas.” (emphasis original) Applicants with all due respect submit that they absolutely do not understand what this sentence means. Does this mean that since Castro does not teach projecting a warm liquid for drying, it must teach projecting warm gas? What is the warm liquid to which the Examiner refers? Is the warm liquid the coating substance, and if so what does that have to do with projection of gas? In the stent art (besides for deposition of a coating) why would there be a teaching about projection of warm liquid to a stent for drying purposes since if it is a goal to dry the polymer, then warm liquid is not the most suitable method of drying a wet polymer?

Moreover, by this statement, the Examiner is taking the position that since the reference does not teach A, it must teach B, even though B is not taught by the reference. In other words, the Examiner is trying to establish the existence of B, even though B is lacking, by arguing the lack of existence of A. To be respectfully candid with the Examiner, Applicants do not follow the logic of this reasoning at all. There is no legal precedent that says a claimed element can be illustrated by a reference, even though its not disclosed in that reference, based on the lack of existence of another element. The law on anticipation is very simple, unlike the requirement for obviousness, in that the reference either teaches the element or does not teach the element. Again, the bottom line is that directing or blowing of gas is not disclosed by Castro.

(B) Regardless of the arguments above, Castro, with respect to claim 1, fails to teach “**if the solvent has a vapor pressure greater than 17.54 Torr at ambient temperature the**

temperature of the gas is adjusted to inhibit the evaporation of the solvent, and if the solvent has a vapor pressure of less than 17.54 Torr at ambient temperature the temperature of the gas is adjusted to induce the evaporation of the solvent.” The Examiner has completely disregarded this element. Similarly, with respect to claim 23 Castro fails to teach “wherein if the solvent is non-volatile the temperature of the gas is adjusted to induce the evaporation of the solvent, and if the solvent is volatile the temperature of the gas is adjusted to inhibit the evaporation of the solvent.”

Accordingly, claims 1 and 23 are patentably allowable over Castro. Claims 2-6, 11, 13, 17-19, 21, 22, and 33-36 depend from claim 1 and are allowable for at least the same reason. Claims 24, 44, 46 and 48-53 depend from claim 23 and are allowable for at least the same reason. Withdrawal of the rejection is respectfully requested.

9. Claims 9, 10, 15, 16, 20, 25, 26, 41, and 45 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Castro. As indicated above, claims 1 and 23 are patentably allowable over Castro. Claims 9, 10, 15, 16, 20, 25, 26, 41, and 45 depend from claims 1 and 23 and are allowable for at least the same reason.

10. Claims 1-7, 9-11, 13 and 15-26 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Ding et al. (U.S. Patent No. 6,358,556) (“Ding”) in view of You et al. (U.S. Patent No. 6,407,009) (“You”). Applicants respectfully disagree based on the following reasons:

(A) With respect to claim 1, Ding in combination with You fails to teach each and every element of the claim. Neither Ding nor You teach that the temperature of the gas is based on a **solvent vapor pressure of 17.54 Torr at ambient temperature**, as recited in claim 1. For this reason alone, claim 1 is patentably allowable over Ding in view of You.

(B) With respect to Claim 23, the references alone or in combination fail to teach **“blowing a gas, from a gas blower positioned at a distance from the coating dispenser, directly onto the implantable medical device.”** Ding simply fails to teach the use of any kind of gas blower for blowing gas. In turn, the Applicants assume that the Examiner is relying on You to fulfill this deficiency. However, Applicants submit that You falls short of this teaching. You teaches that “the chamber space 103 can be cooled adiabatically by using the bias gas stored under pressure and released into the chamber at a pressure lower than the storage pressure of the gas” (col. 5 lines 66 and 67 continuing to col. 6, lines 1 and 2). **Releasing gas into a chamber to cool the chamber** holding a semiconductor substrate is not equivalent to **“blowing a gas ... directly onto the implantable medical device.”** Moreover, the You even states that the gas is released at a **pressure lower than the storage pressure**. For this reason alone, Claim 23 is patentably allowable over the combination of the references.

(C) The question presented to the Examiner is very simple: Considering that Ding fails to even remotely discuss problems associated with application of coating to stents (problems such as “cob-web” formation between stent struts, “pool” formation on the struts, drug retention, minimization of interaction of the drug to the solvent (which could adversely affect of the drug) and enabling the stent to hold enough drug for the effective treatment of the patient), **why would one of ordinary skill in the art, in review of Ding, look to fix something that is not even there? The answer is simple: Hindsight, the same hindsight that is being used by the Examiner.**

The Examiner’s position simply is that even though Ding does not disclose any kind of stent coating issues, it is perfectly reasonable for a stent coating technician to look to the art of semiconductor fabrication to cure a problem that is not discussed by Ding. This is the exact kind of reasoning that the Appellate Board and the courts have frowned upon for decades.

(D) One page 8 of the response, the Examiner has stated that “Ding is concerned with forming a conformal, uniform coating by spraying on a rotating substrate and evaporating the solvent. You is concerned with forming a uniform coating by spraying on a rotating substrate and controlling the evaporation of the solvent.” For these reasons the Examiner concluded that the references can be combined.

First, the Ding reference is not concerned with conformal and uniform coating of stents. There is absolutely no disclosure in Ding that problems such as cob-webs and coating uniformities need to be addressed. As indicted by Ding, the “object of the present invention is to provide a coating ... capable of long-term delivery of biologically active materials.” Ding uses a plasma treatment in addressing this issue. Applicants respectfully submit that the Examiner is simply making up that fact that Ding is concerned with conformal and uniform coating without any support whatsoever. If the Applicants’ reading of Ding is incorrect, Applicants kindly ask the Examiner to point out exactly where Ding teaches that the coating has to be conformal or uniform.

Second, Applicants respectfully ask that the Examiner not come back with a statement that one of ordinary skill in the art would want the coating to be conformal and uniform because this statement would be in error. Current studies are being conducted on non-conformal coating based on the stresses that the stent struts apply on the deposited coating. Studies are also being conducted on producing non-conformal coating as a means of varying the drug release rate.

Third, the issues surrounding coating a semiconductor wafer are not equivalent to coating of stents. One is directed at coating a flat, two dimensional, solid structure. The other is directed at coating a three-dimensional tubular structure. One is directed at coating a large (for example 8 inches in diameter), flat surface area. The other is directed at coating struts less and 1 mm in width and gaps or opening between the struts. One is directed at a being open to all forms of

manufacturing processes, while the other is limited to standards that have to be approved by the FDA, including material used.


Applicants can appreciate the fact how easy it is for the Examiner to simply conduct a key word search and find two disparate references that teach a combination of what has been claimed and work backwards to try to justify why the reference can be combined since both are in the field of coating technology. But the fact of the matter is that many companies, including giants such as Johnson and Johnson, Guidant, Boston Scientific, Abbott, and Medtronic have been working on releasing a drug delivery stent into the market for years, some as far back as 10 years, and so far only two, Johnson and Johnson and Boston Scientific have a product in the market. This being said, Boston Scientific has had a big product recall based on manufacturing problems that they encountered. This is well documented news. So the fact of the matter is, for the Examiner to trivialize this invention by trying to justify the applicability of a semiconductor reference to the invention at hand is unfair and unreasonable to the Applicants.

CONCLUSION

In sum, Applicants respectfully request withdrawal of all the rejections and allowance of the claims. Applicants respectfully request issuance of the notice of allowance. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0323.

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Respectfully submitted,



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